UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. ____________

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, as for its Complaint regarding a Freedom of Information Act request against the above-captioned Defendant, alleges as follows:

INTRODUCTION

1. Until only a few weeks ago, all coronavirus vaccines available in the United States were only authorized for emergency use by the U.S. Food and Drug Administration (the "**FDA**").[1]

2. On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty (the "**Pfizer Vaccine**") for individuals 16 years of age and older.[2]

3. Although the FDA asserts that the Pfizer Vaccine "meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product[,]"[3] numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the

[1] https://www.bmj.com/content/373/bmj.n1244 (last visited 9/5/2021).
[2] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 9/5/2021).
[3] *Id.*

analyses relied upon by the FDA to license the Pfizer Vaccine.

4. PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines.

5. In furtherance of its mission, and in an effort to ensure that the FDA acts in furtherance of its commitment to transparency,[4] PHMPT seeks to obtain the data and information relied upon by the FDA to license the Pfizer Vaccine. The importance of releasing to the public this information is also recognized under federal law which provides that: "After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. (2) A protocol for a test or study . . ." 21 C.F.R. § 601.51(e).

6. PHMPT therefore issued a request to the FDA pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**") for "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[5] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[6]" (the "**FOIA Request**").

7. The medical and scientific community and the public have a substantial interest in reviewing the data and information underlying the FDA's approval of the Pfizer Vaccine.

[4] https://www.fda.gov/about-fda/transparency (last visited 9/5/2021).

[5] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[6] For the avoidance of doubt, the FOIA Request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

Reviewing this information will settle the ongoing public debate regarding the adequacy of the FDA's review process. Releasing this data should also confirm the FDA's conclusion that the Pfizer Vaccine is safe and effective and, thus, increase confidence in the Pfizer Vaccine. The public's need for this information is urgent given the fact that COVID-19 vaccines are being mandated to individuals across the country by federal, state, and local governments as well as private businesses.

8. In an effort to disseminate the requested information to the public as expeditiously as possible, given the time sensitive nature of the issue, PHMPT requested expedited processing of the FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II).

9. On September 9, 2021, the FDA denied PHMPT's request for expedited processing on the basis that PHMPT did "not demonstrate[] a compelling need that involves an imminent threat to the life or physical safety of an individual" or "that there exists an urgency to inform the public concerning actual or alleged Federal Government activity." PHMPT brings this action to challenge the FDA's determination and seeks an order compelling the FDA to produce responsive records on an expedited basis.

PARTIES

10. Public Health and Medical Professionals for Transparency is a not-for-profit organization with an office located at 1090 Texan Trail, Suite 534, Fort Worth, Texas, 76051.

11. PHMPT's members include:

a. **Aaron Kheriaty, MD**
Professor of Psychiatry, UCI School of Medicine
Director, Medical Ethics Program, UCI Health

b. **Harvey Risch, MD, PhD**
Professor of Epidemiology
Yale School of Public Health

c. **Peter A. McCullough,** MD, MPH, FACP, FACC, FCCP, FAHA, FNKF, FNLA, FCRSA

d. **Carole H Browner, PhD, MPH**
Distinguished Research Professor
UCLA David Geffen School of Medicine

e. **Peter Doshi, PhD**
Associate Professor, Pharmaceutical Health Services Research
University of Maryland School of Pharmacy
Baltimore, Maryland, U.S.A.

f. **Linda Wastila, BSPharm, MSPH, PhD**
Professor, Pharmaceutical Health Services Research
University of Maryland School of Pharmacy

g. **Andrew Bostom, MD, MS**
Associate Professor of Family Medicine (Research)
The Warren Alpert Medical School of Brown University

h. **Erick H. Turner, MD**
Associate Professor
Oregon Health & Science University

i. **Aditi Bhargava, PhD**
Professor Emerita
Department of ObGyn and Reproductive Sciences University of California San Francisco

j. **Joseph A. Ladapo, MD, PhD**
Associate Professor of Medicine
Division of General Internal Medicine and Health Services Research
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k. **Gabe Vorobiof, MD FACC FASE**
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Associate Clinical Professor of Medicine
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Glassboro, New Jersey, U.S.A.

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Newcastle upon Tyne, United Kingdom

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Professor of Genetics
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o. **László G. Boros, MD**
Scientific Advisor
SIDMAP, LLC and the Deutenomics Science Institute

p. **Angela Spelsberg, MD, SM**
Comprehensive Cancer Center Aachen

Aachen, Germany

q. **Christine Stabell Benn, MD, PhD, DMSc**
Professor of Global Health
University of Southern Denmark
Copenhagen, Denmark

r. **Peter Aaby, MSc, DMSc**
Head of Bandim Health Project, Guinea-Bissau
University of Southern Denmark
Copenhagen, Denmark

s. **Ulrich Keil, MD, PhD, FRCP (London)**
Professor Emeritus
University of Muenster
Muenster, Germany

t. **Barbara Mintzes, BA, MSc, PhD**
Associate Professor, School of Pharmacy
The University of Sydney
Sydney, Australia

u. **David Healy, MD FRCPsych**
Professor of Psychiatry
McMaster University
Ontario, Canada

v. **Tom Jefferson, MD MRCGP FFPHM**
Senior Associate Tutor
University of Oxford

w. **Byram W. Bridle, PhD**
Associate Professor of Viral Immunology
Department of Pathobiology
University of Guelph, Ontario

x. **Peter C. Gøtzsche, Professor, DrMedSci, MD, MSc**
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ff. **Dr. Peter Abdelmalak**
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12. The FDA is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. The FDA is an agency within the meaning of 5 U.S.C. § 552(f).

JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

FACTS

A. FDA Approval of the Pfizer Vaccine

14. On August 23, 2021, the FDA approved the Pfizer Vaccine for individuals 16 years of age and older.[7]

15. There is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine.

16. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure.

[7] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 9/5/2021).

17. For example, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that "the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product."[8]

18. Peter Marks, the director of FDA's Center for Biologics Evaluation and Research, made similar remarks, stating that

> [The FDA's] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine's] safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities[.][9]

19. Peter Marks further stated that "although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA's] existing high standards for vaccines in the U.S."[10]

20. President Biden also stated that the FDA's approval meets the "gold standard."[11]

21. Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are "safe and effective."[12]

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[8] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 9/8/2021).

[9] *Id.*

[10] *Id.*

[11] https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/ (last visited 9/8/2021).

[12] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 9/8/2021). *See also* https://www.hhs.gov/ ("COVID-19 vaccines are safe, effective, and free) (last visited 9/8/2021); https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 9/8/2021); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 9/8/2021); https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/ (quoting Governor Whitmer referring to the Pfizer Vaccine as a "safe, effective COVID-19

22. On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine, including a number of the scientists and journalists that are members of PHMPT.

23. For example, on June 1, 2021, a group of 27 clinicians and scientists, including professors from Harvard Medical School and the UCLA School of Public Health, and members of PHMPT, filed a Citizen Petition[13] with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[14]

24. Separately, Professor Peter Doshi, a PHMPT member, has publicly questioned the lack of transparency regarding the vaccine approval process,[15] which Peter Marks publicly disputed.[16] For example, Peter Doshi publicly claimed that the FDA's EUA review of the Pfizer Vaccine "seem[ed] wholly inadequate" because it "assigned only a single reviewer in each of two key scientific disciplines (clinical and statistics) to do the work in three weeks that usually takes months to do."[17] In response, Peter Marks asserted that the reviewers Doshi referred to "are simply the leads for each review discipline" but failed to identify a single additional individual involved

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vaccine") (last visited 9/8/2021).

[13] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 9/8/2021).

[14] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 9/8/2021).

[15] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 9/8/2021); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 9/8/2021); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 9/8/2021).

[16] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/ (last visited 9/8/2021).

[17] *Id.*

in the review.[18]

25. Peter Doshi has also questioned the adequacy of the data on the basis that the Pfizer Vaccine is only "13 months into the still ongoing, two year pivotal trial, with no reported data past 13 March 2020, unclear efficacy after six months due to unblinding, evidence of waning protection irrespective of the Delta variant, and limited reporting of safety data."[19]

26. Andrew Kheriaty, professor of psychiatry at UCI School of Medicine, Director of the Medical Ethics Program at UCI Health,[20] and also a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[21] by the FDA's Vaccines and Related Biological Products Advisory Committee ("**VRBPAC**") that indicates a risk of heart inflammation after vaccination.[22]

27. Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]"[23] Despite all eyes on the COVID-19 vaccines and calls for transparency regarding the FDA's actions, the FDA did not convene its advisory group, VRBPAC, to have a public meeting prior to licensure. Those interested were denied the opportunity to both hear discussion about the data and to offer public comment about same.

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[18] *Id.*

[19] https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 9/8/2021).

[20] https://www.aaronkheriaty.com/bio (last visited 9/8/2021).

[21] https://www.fda.gov/media/150054/download (last visited 9/8/2021).

[22] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 9/8/2021).

[23] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 9/8/2021). *See also* https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/ (last visited 9/8/2021).

B. Vaccine Requirements

28. Over the objections of many, the Pfizer Vaccine is being mandated to individuals across the country by the federal government,[24] local governments,[25] public and private employers,[26] universities, [27] schools,[28] and various other institutions,[29] and many more entities are expected to follow suit.[30]

29. At the federal level, legislation was recently introduced that would require COVID-

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[24] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 9/8/2021); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 9/8/2021); https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f (last visited 9/8/2021); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 9/8/2021).

[25] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 9/8/2021); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 9/8/2021); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 9/8/2021).

[26] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 9/8/2021); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 9/8/2021); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 9/8/2021); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 9/8/2021); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 9/8/2021); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 9/8/2021); https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates (last visited 9/8/2021); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 9/8/2021).

[27] *See* https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/ (last visited 9/8/2021). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 9/8/2021); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 9/8/2021); https://uhs.berkeley.edu/requirements/covid19 (last visited 9/8/2021); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 9/8/2021); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 9/8/2021); https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing (last visited 9/8/2021)

[28] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 9/8/2021); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 9/8/2021); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 9/8/2021); https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html (last visited 9/8/2021); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 9/8/2021).

[29] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 9/8/2021); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 9/8/2021); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 9/8/2021); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 9/8/2021); https://www.cdph.ca.gov/Programs/CID/DCDC

19 vaccines for air travel into or out of the United States[31] and the Pentagon has mandated COVID-19 vaccines for all military personnel.[32] In addition, Present Biden recently announced vaccine mandates for all employers with 100 or more employees, all federal employees, and all employees of federal contractors.[33]

30. At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[34] all state employees, [35] and even for all citizens of the state.[36]

31. As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates will follow FDA approval of a COVID-19 vaccine[37] and President Biden is actively encouraging "companies in the private sector to step up the vaccine requirements[.]"[38]

/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 9/8/2021); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 9/8/2021); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 9/8/2021); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 9/8/2021).

30 *See* https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/ (last visited 9/8/2021); https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657 (last visited 9/8/2021); https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd (last visited 9/8/2021). *See also* https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate (last visited 9/8/2021).

31 https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 8/23/2021).

32 https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 8/23/2021).

33 https://www.whitehouse.gov/covidplan/ (last visited 9/13/2021). *See also* https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html (last visited 9/13/2021).

34 *See* New York bill S6495 available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 9/8/2021).

35 *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 9/8/2021).

36 *See* New York bill A11179 available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 9/8/2021).

37 https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 9/8/2021).

38 https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 9/8/2021). *See also* https://www.nytimes.com/2021/08/23/us/pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 8/23/2021); https://www.msn.com/en-us/news/us/now-

32. More recently, it appears that mandates may now encompass additional booster shots of the vaccine in order to retain a "fully vaccinated" status.[39]

C. The FOIA Request

33. In furtherance of PHMPT's mission to disseminate information to the public, and in an effort to ensure that the FDA acts consistently with its commitment to transparency,[40] on August 27, 2021, PHMPT submitted the FOIA Request to the FDA. Pursuant to the FOIA Request, PHMPT requested that the following documents be produced on an expedited basis:

> **All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[41] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[42]**

(**Exhibit A.1.**)[43]

34. Upon submitting the FOIA Request, PHMPT immediately received confirmation that the FOIA Request was submitted successfully. (**Exhibit A.2**.)

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that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 8/23/2021); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 8/23/2021).

[39] *See* https://www.nbcnews.com/health/health-news/u-s-announces-plan-offer-boosters-all-americans-starting-late-n1277059 (quoting the U.S. Surgeon General stating "it is our clinical judgment that the time to lay out a plan for Covid-19 boosters is now") (last visited 9/13/2021); https://www.youtube.com/watch?v=ciVGAPuruoQ at 17:21 (video of Rochelle P. Walensky, Director of the CDC, stating "we are planning for Americans to receive booster shots") (last visited 9/13/2021).

[40] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 9/5/2021).

[41] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[42] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

[43] All "Exhibits" referenced herein are attached to this Complaint.

35. On August 31, 2021, the FDA issued an acknowledgment and assigned case number 2021-5683 to the FOIA Request. (**Exhibit A.3**.)

D. <u>Request for Expedited Processing</u>

36. In the FOIA Request, PHMPT requested that the FDA process the FOIA Request on an expedited basis pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II).

37. On September 9, 2021, the FDA denied PHMPT's request for expedited processing of the FOIA Request (the "**Denial Letter**").[44] In the Denial Letter, the FDA stated in relevant part:

> I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(**Exhibit A.4**.)

<u>ARGUMENT</u>

38. FOIA provides for "expedited processing of request for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(II). When the person requesting information is "primarily engaged in disseminating information urgency to inform the public concerning actual or alleged Federal Government activity" constitutes a "compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(v)(II).

39. PHMPT requested expedited processing of the FOIA Request on the basis that it is "primarily engaged in disseminating information" and that there is an "urgency to inform the public concerning actual or alleged Federal Government activity." In the Denial Letter, the FDA

[44] The FOIA requires federal agencies to issue determinations on requests for expedited processing within ten days from the date of the request. 5 U.S.C. § 552(a)(6)(E)(ii)(I). The FDA's denial of PHMPT's request for expedited processing was issued 13 days after PHMPT issued the FOIA Request.

challenged PHMPT's request for expedited processing only on the basis that PHMPT allegedly failed to "demonstrate[] a compelling need that involves an imminent threat to the life or physical safety of an individual" or "that there exists an urgency to inform the public concerning actual or alleged Federal Government activity." As explained below, the FDA is wrong as there is an urgent need for the medical and scientific community and the public to review the data and information underlying the FDA's approval of the Pfizer Vaccine.

40. The FDA does not and cannot challenge that PHMPT is "primarily engaged in disseminating information." PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to the FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various

platforms, including through interviews,[45] articles,[46] blogs,[47] essays,[48] and podcasts.[49] Therefore, PHMPT and many of its members are "primarily engaged in disseminating information to the general public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," here, the data and information underlying the licensure by the FDA of the Pfizer Vaccine.

41. In determining whether there is "urgency to inform the public," courts consider: "(1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity." *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.D.C. 2001). All three factors are present here.

42. The FOIA Request concerns a matter of current exigency to the American public.

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[45] *See, e.g.*, https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role (Harvey Risch) (last visited 8/26/2021)

[46] *See, e.g.*, https://www.bmj.com/content/373/bmj.n1244 (Peter Doshi) (last visited 9/8/2021); https://www.bmj.com/content/371/bmj.m4058 (Peter Doshi) (last visited 9/8/2021); https://www.bmj.com/content/371/bmj.m4037 (Peter Doshi) (last visited 9/8/2021); https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749 (last visited 8/25/2021); https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (Aaron Kheriaty and Gerard V. Bradley) (last visited 9/8/2021); https://thefederalist.com/2021/07/05/how-college-covid-vaccine-mandates-put-students-in-danger/ (Andrew Bostom, Aaron Kheriaty, Peter A. McCullough, Harvey A. Rish, Michelle Cretella, and Gerard V. Bradley) (last visited 9/8/2021); https://thefederalist.com/2021/08/18/why-forcing-unvaccinated-students-to-wear-cloth-masks-is-anti-science/ (Andrew Bostom, Gerard Bradley, Aaron Kheriaty, and Harvey Risch) (last visited 9/8/2021); https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf (Serena Tinari and Catherine Riva) (last visited 9/8/2021); https://www.bmj.com/content/372/bmj.n627 (Serena Tinari) (last visited 9/8/2021); https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735 (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi) (last visited 9/8/2021); https://www.arcdigital.media/p/medical-ethicist-sues-the-university (Justin Lee) (last visited 9/8/2021).

[47] *See, e.g.*, https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (Peter Doshi) (last visited 9/8/2021); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (Peter Doshi) (last visited 9/8/2021). *See also* https://www.re-check.ch/wordpress/en/covid-certificate/ (Catherine Riva and Serena Tinari) (last visited 9/8/2021).

[48] *See* https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/ (Andrew Bostom) (last visited 9/8/2021).

[49] *See, e.g.*, https://www.andrewbostom.org/2021/05/dr-andrew-bostom-discusses-the-unfavorable-risk-benefit-ratio-of-covid-19-vaccination-of-very-low-covid-19-risk-12-to-17-year-olds-with-pfizers-emergency-use-authorization-only-mrna-vaccine/ (Andrew Bostom) (last visited 9/8/2021).

The FDA itself acknowledges this exigency in the Code of Federal Regulations, which expressly provides that "[a]fter a license has been issued, the following data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. . . ." 21 C.F.R. § 601.51(e) (emphasis added). The FDA's own regulations thus expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* The FDA's regulation not only supports the need for expedited treatment under FOIA but is also an independent legal basis that requires expedited treatment of the FOIA Request.

43. This policy is not surprising given the FDA's commitment to transparency and its entire program to assure transparency, because a lack of transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA.[50]

44. Beyond the FDA's own regulations which admit the urgent need for transparency and immediate disclosure in this situation, there are two additional reasons that warrant expedited treatment of this request.

45. First, as explained above, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine.

46. Although public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and

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[50] https://www.fda.gov/about-fda/transparency (last visited 9/8/2021). As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both "safe" and "effective." 21 C.F.R. 601.2(a). The FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download (last visited 9/8/2021). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 9/8/2021); https://www.fda.gov/about-fda/what-we-do (last visited 9/8/2021).

information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure,[51] numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine, including a number of the scientists and journalists that are members of PHMPT.[52]

47. The public debate is unlikely to be settled without full disclosure of the data and information underlying the FDA's conclusion that the Pfizer Vaccine is "safe and effective."

48. Given the widespread and ongoing public debate, the medical and scientific community and the public has an immediate need to review the data and information underlying the licensure of the Pfizer Vaccine. Public disclosure of this information will inform this ongoing public debate.

49. There is also an urgent need for the public to have immediate access to the data and information underlying the licensure of the Pfizer Vaccine because, over the objections of many, this product is being mandated to individuals across the country by the federal government,[53] local

[51] *See, e.g.*, *supra* ¶¶ 16-21.

[52] *See, e.g.*, *supra* ¶¶ 22-27.

[53] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 9/8/2021); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 9/8/2021); https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f (last visited 9/8/2021); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 9/8/2021).

governments,[54] public and private employers,[55] universities,[56] schools,[57] and various other institutions,[58] and many are expected to follow suit.[59]

50. During a time when COVID-19 vaccine mandates are being implemented[60] over

[54] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 9/8/2021); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 9/8/2021); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 9/8/2021).

[55] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 9/8/2021); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 9/8/2021); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 9/8/2021); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 9/8/2021); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 9/8/2021); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 9/8/2021); https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates (last visited 9/8/2021); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 9/8/2021).

[56] *See* https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/ (last visited 9/8/2021). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 9/8/2021); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 9/8/2021); https://uhs.berkeley.edu/requirements/covid19 (last visited 9/8/2021); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 9/8/2021); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 9/8/2021); https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing (last visited 9/8/2021)

[57] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 9/8/2021); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 9/8/2021); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 9/8/2021); https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html (last visited 9/8/2021); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 9/8/2021).

[58] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 9/8/2021); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 9/8/2021); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 9/8/2021); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 9/8/2021); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 9/8/2021); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 9/8/2021); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 9/8/2021); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 9/8/2021).

[59] *See* https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/ (last visited 9/8/2021); https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657 (last visited 9/8/2021); https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd (last visited 9/8/2021). *See also* https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate (last visited 9/8/2021).

[60] *See, e.g.*, *supra* ¶¶ 28-32.

the objection of those that have questions about the data and information supporting the safety and efficacy of the Pfizer Vaccine, and individuals with these questions are being expelled from employment, school, transportation, restaurants, entertainment facilities, and the military, the public has an urgent and immediate need to have access to this data. The urgent need for the public to review this data is heightened by President Biden's recent announcement of vaccine mandates for millions of Americans, including employers with 100 or more employees, federal employees, and employees of federal contractors.[61]

51. PHMPT will forthwith disseminate any information it obtains in response to the FOIA Request. PHMPT, as an entity primarily engaged in disseminating information, has a recognized interest in timely contributing to the ongoing public debate regarding the adequacy of the data and information underlying the FDA's approval of the Pfizer Vaccine.

52. Finally, the information PHMPT seeks concerns actual or alleged federal government activity – namely, whether the FDA properly approved the Pfizer Vaccine based on adequate data and information. The FDA, which is committed to transparency, should immediately release the information PHMPT seeks in the FOIA Request.

53. Because the FDA denied PHMPT's request for expedited processing, PHMPT is entitled to immediately seek relief in this Court. 5 U.S.C. § 552(a)(6)(E)(iii).

Requested Relief

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an Order directing the FDA to produce all documents responsive to the FOIA Request on an expedited basis and in no event later than 10 days from the date of

[61] https://www.whitehouse.gov/covidplan/ (last visited 9/13/2021). *See also* https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html (last visited 9/13/2021).

any such order;

c. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

d. Grant such other and further relief as the Court may deem just and proper.

Dated: September 16, 2021

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Exhibit A.1

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FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL August 27, 2021

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Pfizer-BioNTech COVID-19 Vaccine Biological Product File (IR#0546)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**").

On August 23, 2021, the Food and Drug Administration ("**FDA**") approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty (the "**Pfizer Vaccine**") for individuals 16 years of age and older. On behalf of PHMPT and its individual members, please provide the following records to foia@sirillp.com in electronic form:

All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[1] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[2]

[1] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[2] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

Expedited Processing Requested

PHMPT requests expedited processing for this request. FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(II). When the person requesting information is "primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity" constitutes a "compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(v)(II).

PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews,[3] articles,[4] blogs,[5] essays,[6] and podcasts.[7] Therefore, PHMPT and many of its members are "primarily engaged in disseminating information to the general public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," here, the data and information underlying the licensure of the Pfizer Vaccine. Accordingly, expedited processing of this request is warranted.

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[3] *See, e.g.*, https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role (Harvey Risch) (last visited 8/26/2021)

[4] *See, e.g.*, https://www.bmj.com/content/373/bmj.n1244 (Peter Doshi) (last visited 8/27/2021); https://www.bmj.com/content/371/bmj.m4058 (Peter Doshi) (last visited 8/27/2021); https://www.bmj.com/content/371/bmj.m4037 (Peter Doshi) (last visited 8/27/2021); https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749 (last visited 8/25/2021); https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (Aaron Kheriaty and Gerard V. Bradley) (last visited 8/27/2021); https://thefederalist.com/2021/07/05/how-college-covid-vaccine-mandates-put-students-in-danger/ (Andrew Bostom, Aaron Kheriaty, Peter A. McCullough, Harvey A. Rish, Michelle Cretella, and Gerard V. Bradley) (last visited 8/27/2021); https://thefederalist.com/2021/08/18/why-forcing-unvaccinated-students-to-wear-cloth-masks-is-anti-science/ (Andrew Bostom, Gerard Bradley, Aaron Kheriaty, and Harvey Risch) (last visited 8/27/2021); https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf (Serena Tinari and Catherine Riva) (last visited 8/27/2021); https://www.bmj.com/content/372/bmj.n627 (Serena Tinari) (last visited 8/27/2021); https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735 (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi) (last visited 8/27/2021); https://www.arcdigital.media/p/medical-ethicist-sues-the-university (Justin Lee) (last visited 8/27/2021).

[5] *See, e.g.*, https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (Peter Doshi) (last visited 8/27/2021); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (Peter Doshi) (last visited 8/27/2021). *See also* https://www.re-check.ch/wordpress/en/covid-certificate/ (Catherine Riva and Serena Tinari) (last visited 8/27/2021).

[6] *See* https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/ (Andrew Bostom) (last visited 8/27/2021).

[7] *See, e.g.*, https://www.andrewbostom.org/2021/05/dr-andrew-bostom-discusses-the-unfavorable-risk-benefit-ratio-of-covid-19-vaccination-of-very-low-covid-19-risk-12-to-17-year-olds-with-pfizers-emergency-use-authorization-only-mrna-vaccine/ (Andrew Bostom) (last visited 8/27/2021).

Recognizing the urgency to inform the public concerning the data and information underlying a licensed vaccine, the Code of Federal Regulations expressly provides that "[a]fter a license has been issued, the following data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information…" 21 C.F.R. § 601.51(e) (emphasis added). The FDA's own regulations thus expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* The FDA's regulation not only supports the need for expedited treatment under FOIA but is also an independent legal basis that requires expedited treatment of this request.

This policy is not surprising given the FDA's commitment to transparency and its entire program to assure transparency, because a lack of transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA.[8] There is an urgent public need for such transparency with regard to the Pfizer Vaccine. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both "safe" and "effective."[9] 21 C.F.R. 601.2(a). On August 23, 2021, the FDA granted approval to the Pfizer Vaccine[10] and, beyond the FDA's own regulations which admit the urgent need for transparency and disclosure in this situation, there are two additional reasons that warrant expedited treatment of this request.

First, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Pfizer Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Pfizer Vaccine is more than sufficient for licensure. For example, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that "the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product."[11] Peter Marks, the director of FDA's Center for Biologics Evaluation and Research, made similar remarks, stating that

> [The FDA's] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We

[8] https://www.fda.gov/about-fda/transparency (last visited 8/27/2021).

[9] The FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download (last visited 8/27/2021). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 8/27/2021); https://www.fda.gov/about-fda/what-we-do (last visited 8/27/2021).

[10] *See* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 8/27/2021). *See also* https://www.cnn.com/2021/08/23/health/fda-approval-pfizer-covid-vaccine/index.html (last visited 8/27/2021). The Washington Post claims that approval of the Pfizer Vaccine was the "fastest in the agency's history." https://www.washingtonpost.com/health/2021/08/23/pfizer-vaccine-full-approval/ (last visited 8/27/2021).

[11] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited 8/27/2021).

> evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine's] safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities[.][12]

Peter Marks further stated that "although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA's] existing high standards for vaccines in the U.S."[13] President Biden also stated that the FDA's approval meets the "gold standard."[14] Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are "safe and effective."[15]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and appropriateness of the analyses relied upon to license the Pfizer Vaccine, including a number of the scientists and journalists that are members of PHMPT. For example, on June 1, 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, senior editor for The BMJ and associate professor of pharmaceutical health services research at the University of Maryland School of Pharmacy,[16] and Peter A. McCullough, professor of medicine at Texas A&M College of Medicine, filed a Citizen Petition[17] with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[18] Separately, Peter Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[19] which Peter Marks publicly disputed.[20] Andrew Kheriaty, professor of psychiatry at UCI

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[12] *Id.*

[13] *Id.*

[14] https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/ (last visited 8/27/2021).

[15] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 8/27/2021). *See also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 8/27/2021); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 8/27/2021); https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/ (quoting Governor Whitmer referring to the Pfizer Vaccine as a "safe, effective COVID-19 vaccine") (last visited 8/27/2021).

[16] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 8/27/2021).

[17] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 8/27/2021).

[18] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 8/27/2021).

[19] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 8/27/2021); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 8/27/2021); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 8/27/2021).

[20] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/ (last visited 8/27/2021).

School of Medicine, Director of the Medical Ethics Program at UCI Health,[21] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[22] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[23] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]"[24] PHMPT incorporated by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse and debate regarding the Pfizer Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific community and the public has an immediate need to review the data and information underlying the licensure of the Pfizer Vaccine. Public disclosure of this information will inform this ongoing public debate. Releasing this data should also confirm the FDA's conclusion and thus increase confidence in the safety and efficacy of the Pfizer Vaccine. The FDA should produce the data and information necessary to address this widespread public debate by immediately producing the information requested in this FOIA request.

There is also an urgent need for the public to have immediate access to the data and information underlying the licensure of the Pfizer Vaccine because, over the objections of many, this product is being mandated to individuals across the country by the federal government,[25] local

[21] https://www.aaronkheriaty.com/bio (last visited 8/27/2021).

[22] https://www.fda.gov/media/150054/download (last visited 8/27/2021).

[23] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 8/27/2021).

[24] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 8/27/2021). *See also* https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/ (last visited 8/27/2021).

[25] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 8/27/2021); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 8/27/2021); https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f (last visited 8/27/2021); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 8/27/2021).

governments,[26] public and private employers,[27] universities,[28] schools,[29] and various other institutions,[30] and many are expected to follow suit.[31] At the federal level, legislation was recently introduced that would require COVID-19 vaccines for air travel into or out of the United States[32] and the Pentagon has mandated the COVID-19 vaccines for all military personnel.[33] At the state

[26] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 8/27/2021); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 8/27/2021); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 8/27/2021).

[27] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 8/27/2021); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 8/27/2021); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 8/27/2021); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 8/27/2021); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 8/27/2021); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 8/27/2021); https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates (last visited 8/27/2021); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 8/27/2021).

[28] *See* https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/ (last visited 8/27/2021). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 8/27/2021); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 8/27/2021); https://uhs.berkeley.edu/requirements/covid19 (last visited 8/27/2021); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 8/27/2021); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 8/27/2021); https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing (last visited 8/27/2021)

[29] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 8/27/2021); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 8/27/2021); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 8/27/2021); https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html (last visited 8/27/2021); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 8/27/2021).

[30] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 8/27/2021); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 8/27/2021); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 8/27/2021); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 8/27/2021); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 8/27/2021); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 8/27/2021); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 8/27/2021); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 8/27/2021).

[31] *See* https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/ (last visited 8/27/2021); https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657 (last visited 8/27/2021); https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd (last visited 8/27/2021). *See also* https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate (last visited 8/27/2021).

[32] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 8/23/2021).

[33] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 8/23/2021).

level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[34] all state employees, [35] and even for all citizens of the state.[36] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates will follow FDA approval of a COVID-19 vaccine[37] and President Biden is actively encouraging "companies in the private sector to step up the vaccine requirements[.]"[38] During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Pfizer Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse and debate regarding mandated or potential mandates of the Pfizer Vaccine.

PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

PHMPT is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the Pfizer Vaccine and the clinical trials underlying the FDA's approval of same. The information PHMPT requests will not contribute to any commercial activities.

Note that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the

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[34] *See* New York bill S6495 available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 8/27/2021).

[35] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 8/27/2021).

[36] *See* New York bill A11179 available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 8/27/2021).

[37] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 8/27/2021).

[38] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 8/27/2021). *See also* https://www.nytimes.com/2021/08/23/us/pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 8/23/2021); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 8/23/2021); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 8/23/2021).

public interest. Such statements may help to avoid unnecessary appeal and litigation. PHMPT reserves all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and PHMPT may immediately file an administrative appeal or an action.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact Aaron Siri at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth Brehm, Esq.
Gabrielle G. Palmer, Esq.

Exhibit A.2

U.S. Food and Drug Administration

FOIA Request Confirmation

Confirmation Number: FDA2176603

Requester:

General

Description of Requester:	**Consumer**
Max Amount Willing to Pay:	**$25.00**

Organization

Organization Name:	**Public Health and Medical Professionals for Transparency**				
Primary Phone:	**212-532-1091**	Other Phone:		Email:	**foia@sirillp.com**

Mailing Address

Address 1:	**200 Park Avenue**
Address 2:	**17th Floor**
City:	**New York**
State:	**NY**
Zip Code:	**10166**

Billing Address

Address 1:	**200 Park Avenue**
Address 2:	**17th Floor**
City:	**New York**
State:	**NY**
Zip Code:	**10166**

Details

Requester Name:	**Aaron Siri**		
Requester File #:	**IR#0546**	Request Letter:	**IR#0546 - FDA - Pfizer Approval FINAL.pdf**
Requested Date From:		Requested Date To:	
Subject of Request:	**All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine**		

Waiver of Fees

Justification:	**PHMPT is a nonprofit. The information it seeks will contribute to the public debate about the safety and efficacy of the Pfizer vaccine. See letter for further details.**

Expedited Processing

Reason:	**Demonstrated Urgency to Inform the Public**
Justification:	**PHMPT disseminates information to the public. There is an immediate need to inform the public of the data and information underlying licensure of the Pfizer Vaccine. See letter for further details.**

Print Create Another Request Close

Within 10 business days of the submission of your online request, you will receive by electronic mail an FOIA Control Number. If you need to communicate with FDA regarding your request, please refer to this Control Number. Requests received after 4:00 P.M. E.S.T. will be considered to have been received on the following business day.

If your informational needs change, and you need to cancel your request, please contact the Division of Freedom of Information by telephone, mail, or fax. Please include your control number in the correspondence. For contact information, please see FDA's FOIA page.

Exhibit A.3

U.S. FOOD & DRUG ADMINISTRATION

August 31, 2021

In Reply refer to
FOIA Control #:
2021-5683

Requester reference:

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
AARON SIRI
200 Park Avenue
17th Floor
New York NY 10166 USA

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Claire B. Stansbury, Information Technician, at (301) 796-8979 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

Exhibit A.4

U.S. FOOD & DRUG
ADMINISTRATION

September 09, 2021

In Reply refer to
FOIA Control #:
2021-5683

Requester reference:
IR#0546

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR
TRANSPARENCY
AARON SIRI
200 Park Avenue
17th Floor
New York NY 10166 USA

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director

JS 44 (Rev. 10/20) - TXND (10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY

(b) County of Residence of First Listed Plaintiff: Tarrant
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Howie Law PC / 2608 Hibernia Street, Dallas Texas 75204
(212) 622-6340

DEFENDANTS

FOOD AND DRUG ADMINISTRATION

County of Residence of First Listed Defendant: ______
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- [ ] 1 U.S. Government Plaintiff
- [ ] 3 Federal Question *(U.S. Government Not a Party)*
- [x] 2 U.S. Government Defendant
- [ ] 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	[ ] 1	[ ] 1	Incorporated *or* Principal Place of Business In This State	[ ] 4	[ ] 4
Citizen of Another State	[ ] 2	[ ] 2	Incorporated *and* Principal Place of Business In Another State	[ ] 5	[ ] 5
Citizen or Subject of a Foreign Country	[ ] 3	[ ] 3	Foreign Nation	[ ] 6	[ ] 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- [ ] 110 Insurance
- [ ] 120 Marine
- [ ] 130 Miller Act
- [ ] 140 Negotiable Instrument
- [ ] 150 Recovery of Overpayment & Enforcement of Judgment
- [ ] 151 Medicare Act
- [ ] 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- [ ] 153 Recovery of Overpayment of Veteran's Benefits
- [ ] 160 Stockholders' Suits
- [ ] 190 Other Contract
- [ ] 195 Contract Product Liability
- [ ] 196 Franchise

REAL PROPERTY
- [ ] 210 Land Condemnation
- [ ] 220 Foreclosure
- [ ] 230 Rent Lease & Ejectment
- [ ] 240 Torts to Land
- [ ] 245 Tort Product Liability
- [ ] 290 All Other Real Property

TORTS

PERSONAL INJURY
- [ ] 310 Airplane
- [ ] 315 Airplane Product Liability
- [ ] 320 Assault, Libel & Slander
- [ ] 330 Federal Employers' Liability
- [ ] 340 Marine
- [ ] 345 Marine Product Liability
- [ ] 350 Motor Vehicle
- [ ] 355 Motor Vehicle Product Liability
- [ ] 360 Other Personal Injury
- [ ] 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- [ ] 365 Personal Injury - Product Liability
- [ ] 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- [ ] 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- [ ] 370 Other Fraud
- [ ] 371 Truth in Lending
- [ ] 380 Other Personal Property Damage
- [ ] 385 Property Damage Product Liability

CIVIL RIGHTS
- [ ] 440 Other Civil Rights
- [ ] 441 Voting
- [ ] 442 Employment
- [ ] 443 Housing/ Accommodations
- [ ] 445 Amer. w/Disabilities - Employment
- [ ] 446 Amer. w/Disabilities - Other
- [ ] 448 Education

PRISONER PETITIONS

Habeas Corpus:
- [ ] 463 Alien Detainee
- [ ] 510 Motions to Vacate Sentence
- [ ] 530 General
- [ ] 535 Death Penalty

Other:
- [ ] 540 Mandamus & Other
- [ ] 550 Civil Rights
- [ ] 555 Prison Condition
- [ ] 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- [ ] 625 Drug Related Seizure of Property 21 USC 881
- [ ] 690 Other

LABOR
- [ ] 710 Fair Labor Standards Act
- [ ] 720 Labor/Management Relations
- [ ] 740 Railway Labor Act
- [ ] 751 Family and Medical Leave Act
- [ ] 790 Other Labor Litigation
- [ ] 791 Employee Retirement Income Security Act

IMMIGRATION
- [ ] 462 Naturalization Application
- [ ] 465 Other Immigration Actions

BANKRUPTCY
- [ ] 422 Appeal 28 USC 158
- [ ] 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- [ ] 820 Copyrights
- [ ] 830 Patent
- [ ] 835 Patent - Abbreviated New Drug Application
- [ ] 840 Trademark
- [ ] 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- [ ] 861 HIA (1395ff)
- [ ] 862 Black Lung (923)
- [ ] 863 DIWC/DIWW (405(g))
- [ ] 864 SSID Title XVI
- [ ] 865 RSI (405(g))

FEDERAL TAX SUITS
- [ ] 870 Taxes (U.S. Plaintiff or Defendant)
- [ ] 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- [ ] 375 False Claims Act
- [ ] 376 Qui Tam (31 USC 3729(a))
- [ ] 400 State Reapportionment
- [ ] 410 Antitrust
- [ ] 430 Banks and Banking
- [ ] 450 Commerce
- [ ] 460 Deportation
- [ ] 470 Racketeer Influenced and Corrupt Organizations
- [ ] 480 Consumer Credit (15 USC 1681 or 1692)
- [ ] 485 Telephone Consumer Protection Act
- [ ] 490 Cable/Sat TV
- [ ] 850 Securities/Commodities/ Exchange
- [ ] 890 Other Statutory Actions
- [ ] 891 Agricultural Acts
- [ ] 893 Environmental Matters
- [x] 895 Freedom of Information Act
- [ ] 896 Arbitration
- [ ] 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- [ ] 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- [x] 1 Original Proceeding
- [ ] 2 Removed from State Court
- [ ] 3 Remanded from Appellate Court
- [ ] 4 Reinstated or Reopened
- [ ] 5 Transferred from Another District *(specify)*
- [ ] 6 Multidistrict Litigation - Transfer
- [ ] 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331

Brief description of cause:
Freedom of Information Act, 5 U.S.C. § 552

VII. REQUESTED IN COMPLAINT:

- [ ] CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: [ ] Yes [x] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE ______ DOCKET NUMBER ______

DATE: Sep 16, 2021

SIGNATURE OF ATTORNEY OF RECORD: /s John Howie

FOR OFFICE USE ONLY

RECEIPT # ______ AMOUNT ______ APPLYING IFP ______ JUDGE ______ MAG. JUDGE ______

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related cases, if any. If a related case exists, whether pending or closed, insert the docket numbers and the corresponding judge names for such cases. A case is related to this filing if the case: 1) involves some or all of the same parties and is based on the same or similar claim; 2) involves the same property, transaction, or event; 3) involves substantially similar issues of law and fact; and/or 4) involves the same estate in a bankruptcy appeal.

Date and Attorney Signature. Date and sign the civil cover sheet.